



JFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Romero et al.

**Application No.** 10/713,791

**Filed:** November 13, 2003

**Confirmation No.** 8756

**For:** METHODS AND KITS FOR  
DETERMINING RISK OF PRE-TERM  
DELIVERY

**Examiner:** Not yet assigned

**Art Unit:** 1645

**Attorney Reference No.** 4239-67284-01

**CERTIFICATE OF MAILING**

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney  
for Applicant(s)

Kevin M. Hayes

Date Mailed September 17, 2004

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. § 1.97(b)(3)**

Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language and/or non-English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Because the present application was filed after June 30, 2003, copies of United States patents and United States published patent applications do not have to be provided to the Patent Office. This requirement of 37 C.F.R. § 1.98(a)(2)(i) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on August 5, 2003 (1276 OG 55). Applicants will provide copies of such patents upon request.

Applicants filed this Information Disclosure Statement ("IDS") before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS.

However, if the Patent Office determines that a fee is required for Applicants to file this IDS,

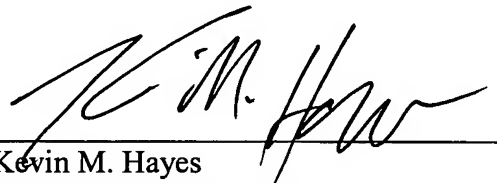
please charge any such fees, or credit overpayment, to Deposit Account No. 02-4550. A duplicate copy of this Information Disclosure Statement is enclosed.

The filing of this IDS shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

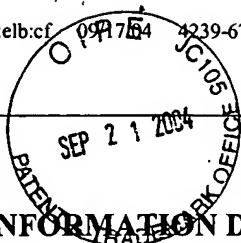
Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By

  
Kevin M. Hayes  
Registration No. 54,158

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 226-7391  
Facsimile: (503) 228-9446  
cc: Client  
Docketing



**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**

Attorney Docket Number	4239-67284-01
Application Number	10/713,791
Filing Date	November 13, 2003
First Named Inventor	Romero
Art Unit	1645
Examiner Name	Not yet assigned

**U.S. PATENT DOCUMENTS**

NOTE: If this application was filed after June 30, 2003, copies of United States patents and United States published patent applications do not have to be provided to the Patent Office. This requirement of 37 C.F.R. § 1.98(a)(2)(i) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on August 5, 2003 (1276 OG 55).

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		5,455,160	10/03/1995	Fagerhol et al.
		5,516,702	05/14/1996	Senyei et al.
		5,972,594	10/26/1999	Heine
		6,174,664	01/16/2001	Heine
		US2003/0175713A1	09/18/2003	Sorg et al.


**FOREIGN PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		PCT	WO 04/43238	05/27/2004	Buhimschi et al..
		PCT	WO 02/42770	05/30/2002	Yoon

**OTHER DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	
		Bhardwaj et al., "The Calcium-Binding Proteins MRP8 and MRP14 Form a Membrane-Associated Heterodimer in a Subset of Monocytes/Macrophages Present in Acute but Absent in Chronic Inflammatory Lesions," EUR. J. IMMUNOL., 22:1891-1897 (1992).
		Merchant et al., "Recent Advancements in Surface-Enhanced Laser Desorption/Ionization-Time of Flight-Mass Spectrometry," ELECTROPHORESIS, 21:1164-1167 (2000).
		Yang et al., "Proinflammatory Properties of the Human S100 Protein S100A12," JOURNAL OF LEUKOCYTE BIOLOGY, 69:986-994 (2001).
		Passey et al., "S100A8: Emerging Functions and Regulation," JOURNAL OF LEUKOCYTE BIOLOGY, 66:549-556 (1999).

EXAMINER SIGNATURE:	DATE CONSIDERED:
<p>* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

<p align="center"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p>		Attorney Docket Number	4239-67284-01
		Application Number	10/713,791
		Filing Date	November 13, 2003
		First Named Inventor	Romero
		Art Unit	1645
		Examiner Name	Not yet assigned
		Romero et al., "Amniotic Fluid White Blood Cell Count: A Rapid and Simple Test to Diagnose Microbial Invasion of the Amniotic Cavity and Predict Preterm Delivery," AM. J. OBSTET. GYNECOL., 165(4 Pt 1):821-30 (1991).	
		Romero et al., "Macrophage Inflammatory Protein-1 $\alpha$ in Term and Preterm Parturition: Effect of Microbial Invasion of the Amniotic Cavity," AM. J. REPROD. IMMUNOL., 32(2):108-13 (1994).	
		Svinarich et al., "Detection of Human Defensin 5 in Reproductive Tissues," AM. J. OBSTET. GYNECOL., 176(2):470-5 (1997).	
		Svinarich et al., "Detection of Human Defensins in the Placenta," AM. J. REPROD. IMMUNOL., 38(4):252-5 (1997).	
		Heine et al., "Amniotic Fluid Defensins: Potential Markers of Subclinical Intrauterine Infection," CLIN. INFECT. DIS., 7(3):513-8 (1998).	
		Yoon et al., "Clinical Significance of Intra-amniotic Inflammation in Patients with Preterm Labor and Intact Membranes," AM. J. OBSTET. GYNECOL., 185(5):1130-6 (2001).	
		Espinoza et al., "Antimicrobial Peptides in Amniotic Fluid: Defensins, Calprotectin and Bacterial/Permeability-increasing Protein in Patients with Microbial Invasion of the Amniotic Cavity, Intra-amniotic Inflammation, Preterm Labor and Premature Rupture of Membranes," J. MATERNAL-FETAL AND NEONATAL MED., 13:2-21 (2003).	
		Romero et al., "Fetal Plasma MMP-9 Concentrations are Elevated in Preterm Premature Rupture of the Membranes," AM. J. OBSTET. GYNECOL., 187(5):1125-30 (2002).	
		Buhimschi et al., "Acute Versus Chronic Inflammation: What Makes the Intra-uterine Environment 'Unfriendly' to the Fetus? From Free Radicals to Proteomics," AMERICAN JOURNAL OF REPRODUCTIVE IMMUNOLOGY, 49(6):350 (2003) (Summary of Oral Presentation).	

EXAMINER SIGNATURE:	DATE CONSIDERED:
<p>* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	